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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/841,188 | 04/25/2001 | John Warrington | 054270-0134 | 3652 |

22428 7590 07/10/2003

FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/10/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/841,188

Applicant(s)

WARMINGTON ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12, 16 and 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' amendments and response of April 28, 2003 in Paper No. 13 is acknowledged. Applicants canceled claims 1-8, 13-15 and 17 and substitute them with new claims 18-37.
2. Currently claims 9-12, 16 and 18-37 are pending. Claims 9-12 and 16 were withdrawn from consideration as being drawn to non elected inventions, however applicants have canceled those claims.
3. Claims 18-37 are under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Abstract

6. An abstract on a separate sheet has been submitted by the applicants.

Objections Withdrawn

7. Objections to the specification made in paragraphs 7 and 8 of the office action mailed 12/26/2002, paper #10 are withdrawn in view of applicants amendments.

Objections Moot

8. Objection to the claim 8 made in paragraph 9 of the office action mailed 12/26/2002, paper #10 is moot in view of cancellation of the claim.

Rejections Moot

9. Rejection of claims 1- 8, 13 and 17 under 35 U.S.C. 112 second paragraph, made in paragraph 10 of the office action mailed 12/26/2002, paper #10 is moot in view of cancellation of the claims.
10. Rejection of claims 1- 8 and 17 under 35 U.S.C. 102 (b), made in paragraph 11 of the office action mailed 12/26/2002, paper #10 is moot in view of cancellation of the claims.
11. Rejection of claim 13 under 35 U.S.C. 103 (a), made in paragraph 12 of the office action mailed 12/26/2002, paper #10 is moot in view of cancellation of the claim.
12. Rejection of claims 14- 15 under 35 U.S.C. 103 (a), made in paragraph 13 of the office action mailed 12/26/2002, paper #10 is moot in view of cancellation of the claims.

New Rejections

Claim Rejections - 35 USC § 112

13. Claims 24-29 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites “antigens for detecting antibodies to *Candida* of 55kDa, 30 kDa and 20 kDa.” It is not clear what these numbers represent?

Claims 24, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting improper Markush group. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group comprising of A, B, and/or C." See *ex parte Markush*, 1925 C.d. 126 (Comm'r Pat. 1925).

Claim Rejections - 35 USC § 102

14. Claims 18-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckley et al. (US 4,806,465).

The claims are drawn to a method of diagnosing *Candida* infection, comprising the steps of:

- a) obtaining a biological sample from a subject;
- b) preparing an antigen composition comprising a soluble cytoplasmic antigen antigen preparation, which is mannose, depleted;
- c) contacting said antigen with said biological sample;
- d) using a detection system to determine if antibodies from the sample are bound to said antigen composition.

Buckley et al. discloses a method of diagnosing *Candida* infection, comprising the steps of:

- a) obtaining a biological sample from a subject (see claims 1-4);
- b) preparing an antigen composition comprising a soluble cytoplasmic antigen antigen preparation which is mannose depleted (see claims 1-4 and column 4, lines 21-26);

- c) contacting said antigen with said biological sample (see claims 1-4);
- d) using a detection system to determine if antibodies from the sample are bound to said antigen composition.

See claims specially claims 1-4 and column 17, lines 45-55.

Buckley et al. teach ELISA, RIA, latex agglutination, immunoblot assay and other suitable antigen detection systems (see columns 2 and 17). Buckley et al. teach antigens having molecular weights of 55 kDa (see figures 6 and 7) 30 kDa (figure 3) and 20 kDa (see figure 3). Buckley et al. teach secondary labeled antibodies, radioisotopes, immunoprecipitation, and qualitative and quantitative detection methods (see examples 1, 2, 3, and 4).

Applicants' arguments filed 4/28/2003 have been fully considered but they are not persuasive.

Applicants argue that:

- 1) Applicants have determined that there is no reactivity between Buckley's antibodies and the claimed antigen preparation when measured via immunoblotting or ELISA.
- 2) Buckley reference describes antigens extracted from the mycelial form of *Candida*, whereas applicants' recited antigens prepared from the blastospore form.
- 3) Molecular weights of disclosed antigens are different.

It is the examiners position that:

In response to the issue (1) applicants have failed to provide the information through a declaration. In response to the issue (2) Buckley reference describes antigens extracted from both the mycelia or yeast form of *Candida* (see column 4, lines 21-25). In response to the issue (3)

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Buckley reference teach multiple antigens including the ones having molecular weights of 55 kDa (see figures 6 and 7) 30 kDa (figure 3) and 20 kDa (see figure 3).

15. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Buckley et al. (US 4,806,465).

The claim is drawn to an antigenic composition comprising a soluble mannose depleted cytoplasmic antigen from *Candida*.

Buckley et al. discloses an antigenic composition comprising a soluble mannose depleted cytoplasmic antigen from *Candida* (see claims 1-4 and column 4, lines 21-26). Buckley et al. teach multiple antigens including the ones having molecular weights of 55 kDa (see figures 6 and 7) 30 kDa (figure 3) and 20 kDa (see figure 3).

16. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al. (US 4,806,465) in view of Miyada et al. (US 5,766,874).

The claims are drawn to a kit for diagnosing *Candida* infection, comprising:

- a) a biological collection device;
- b) an antigenic composition comprising a soluble mannose depleted cytoplasmic antigen from *Candida*; and
- c) means for detecting reaction between the antibody in the sample and antigen composition

Buckley et al. discloses an antigenic composition and method of diagnosing *Candida* infection, comprising of:

- a) a biological collection device;
- b) an antigenic composition comprising a soluble mannose depleted cytoplasmic antigen

from *Candida*; and

c) means for detecting reaction between the antibody in the sample and antigen composition

See claims specially claims 1-4.

Buckley et al. teach ELISA, RIA, latex agglutination, immunoblot assay and other suitable antigen detection systems (see columns 2 and 17). Buckley et al. teach do not teach diagnostic kit. However use of kits in immunodiagnosis are well known in the art for example Miyada et al. teach kits for diagnosis of *Candida* infections (see claims).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to arrange the reagents and material used in the methods of diagnosis taught by Buckley et al. in form of a kit to obtain the instant invention.

One of ordinary skill in the art would have been motivated by the teaching of Miyada et al. to do this in order to obtain a method and a kit to simplify and optimize diagnostic techniques to detect *Candida* infections or disease.

Conclusion

17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday through Friday from 7:30 AM - 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

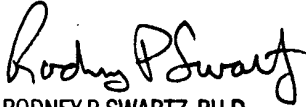
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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July 6, 2003


RODNEY P. SWARTZ, PH.D
PRIMARY EXAMINER